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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,170	09/23/2003	Bruce H. KenKnight	279.565USI	1699

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,170	KENKNIGHT ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-12 and 14-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-12 and 14-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on June 23, 2006. Claims 3 and 13 have been cancelled. Claims 1-2, 4-12 and 14-20 are pending.

Specification

2. In view of the response filed on June 23, 2006, the Examiner has withdrawn the objections to the Specification.

Claim Objections

3. Claims 1-2 and 11-12 are objected to because of the following informalities: there appears to be inadvertent typographical errors in the claims, rendering the language awkward. As to Claim 1, the Examiner suggests moving lines 8-10 down to the end of the claim. As to Claim 11, the Examiner suggests moving lines 6-8 down to the end of the claim. In addition, in regards to both Claims 1 and 11, the Examiner suggests changing the phrase "wherein the cardiac function therapy is multi-site ventricular pacing" to read ""wherein the cardiac function therapy comprises multi-site ventricular pacing" . In regards to Claims 2 and 12, the Examiner suggests revising the claims to read, "wherein the multi-site ventricular pacing improves the patients cardiac pumping performance". Appropriate correction is required.

Response to Arguments

4. Applicant's arguments, see pages 8-9 of the Remarks, filed June 23, 2006, with respect to the rejection(s) of claim(s) 3 and 13 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration,

a new ground(s) of rejection is made in view of a different interpretation of the previously applied reference, Darvish et al. (U.S. 6,292,693) (herein Darvish).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 7, 10-12, 17 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Darvish. As to Claims 1-2, 10-12 and 20, Darvish discloses an implantable device 70 for delivering cardiac function therapy to a patient for improving a patient's cardiac output and providing cardiac resynchronization therapy through multi-site ventricular pacing (see Darvish Fig. 6, column 1, lines 13-16 and column 7, lines 62-64). The implantable device 70 of Darvish comprising sensing channels and pacing channels for sensing cardiac electrical activity at a plurality of myocardial sites and delivering pacing pulses to a plurality of myocardial sites (i.e. right atrium 28, right ventricle 30 and left ventricle 44) (see Dravish Figs. 1 and 6, column 4, lines 42-53 and column 5,lines 1-16). Device 70 also comprises a control logic unit, read as a controller 72 to control the application of electrical energy from electrodes 32, 34 and 46 (see Darvish column 7, lines 65-67) via an algorithm stored in memory 78 (see Darvish column 8, lines 60-64) which defines the pulse output sequence and pulse configuration for delivering cardiac function therapy (see Darvish column 5, lines 1-39). In reference to Darvish Fig. 3, the algorithm programmed into the controller 72 is depicted in flow chart form where the device 70 operates first in a cardiac function therapy (DDI pacing) mode (see Darvish column 6, lines 21-

23), periodically assesses the patient's cardiac output, read as assessing the patient's cardiac function, and re-initiates or continues the delivery of cardiac function therapy based upon the cardiac function assessment (see Darvish Fig. 3). It is inherent that pacing is suspended during the assessment of the patient's cardiac function since Darvish also discloses that the flow chart depicted in Fig. 3 is a "graduated application" to limit the electrical power that must be applied to the heart to prolong battery life and that the algorithm allows the heart muscle "to function in a natural manner as physiological needs will allow and to rest when enhanced cardiac output is not required" (see Darvish column 6, lines 7-20).

Darvish discloses that the cardiac function therapy may be bi-ventricular pacing, read as multi-site ventricular pacing or "any pacing mode known in the art" (see Darvish column 2, lines 48-54 and column 6, lines 24-29). Darvish further discloses that the multi-site ventricular pacing may comprise multi-site ventricular pacing where the right ventricle 30 is paced 3.5 ms before the left ventricle 44, read as a multi-site ventricular pacing which pre-excites the myocardial regions in the right ventricle 30 (see Darvish column 6, lines 62-67 and column 7, lines 1-8). The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case the implantable device 70 of Darvish is capable of pre-exciting the right ventricle 30 in order to redistribute myocardial wall stress during systole for the purpose of reversing ventricular remodeling.

7. As to Claims 7 and 17, Darvish discloses that the cardiac function assessment may include measuring the patient's heart rate variability, which is inherently deterministic of a

patient's autonomic balance since heart rate and variations of heart rate are products of both chains of a person's autonomic nervous system (see Darvish column 6, lines 35-41).

8. Claims 4, 6, 14 and 16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Darvish. As to Claims 4 and 14, Darvish discloses that cardiac output is assessed to be "adequate" via a signal acquired by a physiological sensor sent to controller 72 (see Darvish column 4, lines 1-14). It is inherent or at least obvious to one having ordinary skill in the art that a determination of a signal being "adequate" is accomplished via a microprocessor 74 within controller 72, which compares the sensed signal to a specified threshold value.

9. As to Claims 6 and 16, Darvish discloses that the controller 72 may regulate the pacing algorithm depicted in Fig. 3 responsive to a subject's physical activity by utilizing an accelerometer, read as an exertion level sensor 104 (see Darvish column 9, lines 23-32). It is inherent or at least obvious to one having ordinary skill in the art to compare the output of such exertion level sensor to an exertion level threshold to determine if the pacing algorithm should be modulated or not. Darvish also discloses that cardiac output is assessed to be "adequate" via a signal acquired by a physiological sensor sent to controller 72 (see Darvish column 4, lines 1-14). It is also inherent or at least obvious to one having ordinary skill in the art that a determination of a signal being "adequate" is accomplished via a microprocessor 74 within controller 72, which compares the sensed signal to a specified threshold value.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darvish in view of Burnes (U.S. 2004/0220636). Darvish discloses the claimed invention as discussed above except that the physiological sensor for assessing the patient's cardiac output is not specified to be a trans-thoracic impedance measuring circuit.

Burnes, however, teaches that it is well known to provide an assessment of cardiac output of a patient by using an impedance monitor 162 that that measures transthoracic impedance (see Burnes Fig. 4, page 3, paragraph 29 and page 7, paragraphs 64-65). Burnes does not explicitly state why impedance monitor 162 is used, but it appears that impedance monitor 162 is used to provide a means to asses a patient's cardiac output external to or implanted within the body of a patient (see Burnes page 2, paragraph 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and method as taught by Darvish, with the transthoracic impedance measuring circuit 162 as taught by Burnes, since such a modification would provide the system and method with a transthoracic impedance measuring for providing a means for cariac output to be assessed both internally and externally.

12. Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darvish in view of Zhu et al. (U.S. 2002/020306). Darvish discloses the claimed invention as discussed above except that the method carried out by device 70 does not comprise circuitry for measuring and collecting time intervals between successive chamber senses and storing the collected intervals as a discrete RR interval signal, filtering the RR interval signal into defined high and low frequency bands, and determining the signal power of the RR interval signal in each of the

low and high frequency bands, referred to LF and HF, respectively, and, circuitry for computing an LF/HF ratio and assessing cardiac function by comparing the LF/HF ratio to a specified ratio threshold value.

Zhu, however, discloses that the LF/HF ration is a good indicator of the state of autonomic balance of a patient and discloses circuitry for measuring and collecting time intervals between successive chamber senses, storing the collected intervals as a discrete RR interval signal, filtering the RR interval signal into defined high and low frequency bands, and determining the signal power of the RR interval signal in each of the low and high frequency bands, and computing an LF/HF ratio and triggering a diagnostic mode of the device when the LF/HR exceeds a predetermined ratio threshold value (see Zhu page 5, paragraphs 39-41). It would have been obvious to one having ordinary skill in the art to modify the method and system of Darvish in view of Zhu to comprise circuitry for measuring and collecting time intervals between successive chamber senses and storing the collected intervals as a discrete RR interval signal, filtering the RR interval signal into defined high and low frequency bands, and determining the signal power of the RR interval signal in each of the low and high frequency bands, referred to LF and HF, respectively, and, circuitry for computing an LF/HF ratio and assessing cardiac function by comparing the LF/HF ratio to a specified ratio threshold value to acquire means to switch the device from a therapy mode to a diagnostic mode when necessary.

13. Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darvish in view of Ding (U.S. 2002/0062139). Darvish discloses that the device 70 comprises a telemetry unit 114 coupled to a bi-directional telemetry coil 116 which generally perform similar functions to those performed by pacemaker telemetry apparatuses known in the art. Darvish

discloses the claimed invention as discussed above except that the method carried out by device 70 is not specified to comprise temporarily suspending delivery of cardiac function therapy and assessing the patient's cardiac function upon a command from an external programmer.

Ding, however, discloses an implantable device for delivering cardiac function therapy to a patient (see Ding Fig. 1 and page 2, paragraph 14) comprising atrial and ventricular sensing channels for sensing cardiac electrical activity at a plurality of myocardial sites and atrial and ventricular pacing channels for delivering pacing pulses to a plurality of myocardial sites (see Ding Fig. 1 and page 2, paragraph 15) and a controller 28 made up of a microprocessor 10 communicating with memory 12 and dedicated circuitry for delivering pacing pulses in accordance with a programmed pacing mode (i.e. DDD, DVI, VDD, biventricular or multi-site ventricular pacing) with a defined pulse output sequence and pulse output configuration (see Ding page 2, paragraphs 11 and 14 and page 3, paragraph 16). Ding also discloses that the controller 28 is programmed to temporarily suspend delivery of cardiac function therapy, asses the patient's cardiac function (i.e. monitor changes in the condition of the heart's conduction system by measuring changes in ventricular activation patterns as reflected by electrogram signals detected from different locations in the heart) (see Ding page 1, paragraphs 6-7), and either re-initiate or continue the delivery of cardiac function therapy based upon the cardiac function assessment (see Ding Figs. 2-3, page 2, paragraphs 7 and 11 and page 3, paragraphs 16-17). Specifically, the pacing therapy of Ding "may be adjusted accordingly" in view of the cardiac function assessment (see Ding page 3, paragraph 16).

Ding discloses that the controller 28 may be programmed to temporarily suspend delivery of cardiac function therapy (i.e. pacing) and asses the patient's cardiac function (i.e. changes in

the condition of the heart's conduction system) upon a command from an external programmer via telemetry interface 40 in order to enable an attending physician/clinician to assess whether the patient's conduction system is improving, deteriorating or remaining unchanged so that pacing may be adjusted accordingly (see Ding page 2, paragraphs 13-14 and page 3, paragraph 16 and Claim 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Darvish in view of Ding such that the step of temporarily suspending delivery of cardiac function therapy and assessing the patient's cardiac function is done on command issued by an external programmer in order to enable an attending physician/clinician to assess to have control over the implanted device's operating functions after assessing whether the patient's conduction system is improving, deteriorating or remaining unchanged.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Auricchio et al. (U.S. 6,915,160) discloses a dynamically optimized multi-site cardiac resynchronization device that paces the heart by delivering pacing therapy in a manner that unloads the hypertrophied myocardium to effect reversal of undesirable remodeling.

Bradley (U.S. 6,473,647) discloses a system that tracks the progression or regression of a patient's heart disease, particularly as it relates to the success of any therapy in halting or reversing the remodeling.

Salo (U.S. 6,973,349) discloses a method and apparatus for minimizing post-infarct ventricular remodeling.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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